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(54) **Inhalation device**

Inhalator

Inhalateur

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Description

[0001] This invention relates to an inhalation device according to the preamble of claim 1. Such a device is known from EP-A-0 237 507.

[0002] Medicament for administration by inhalation should be of a controlled particle size in order to achieve maximum penetration in to the lungs, preferably in the range of 1 to 10 micrometers in diameter and more preferably 1 to 5 micrometers. Unfortunately, powders in this particle size range, hereinafter referred to as fine powders, for example micronised powders, usually have very poor flow characteristics. due to the cohesive forces between the individual particles which make them readily agglomerate together to form bridges which are not readily broken apart to become free flowing. These characteristics create handling and metering difficulties which adversely affect the accurate dispensing of doses of the powder. However, co-pending PCT Patent Application No. EP96.03274 (WO-A-97/05018) describes how, by careful sizing of fine agglomerated powder, it is possible to make use of the cohesive forces between the particles to create agglomerates of powder which are free flowing. These agglomerates of powder can be easily handled and may be used to conveniently fill devices.

[0003] However, for efficient delivery to the lungs, the powder agglomerates must be broken down before they leave such a device, back into a controlled size.

[0004] It has been found that it is possible to break up powder agglomerates in the airflow as a user inhales by incorporating a series of baffles in the mouthpiece of a powder inhalation device. EP 0 237 507 describes baffles which comprise helical channel portions which give the airflow a rotating, helical pattern of motion.

[0005] However, one disadvantage associated with the baffles described in EP 0 237 507 in that the baffles comprise a number of components rendering the device manufacturing process relatively complicated and expensive.

[0006] GB 2191718 relates to aerosol devices for dispensing nicotine. The nicotine dispensing device has an impaction means designed to separate the spray allowing the smaller particles and vapour phase to flow around the baffle while the larger particles are removed.

[0007] PCT/EP93/00582 (WO-A-93/18811) also describes a device comprising baffles which are acting as separators, but if the aerosol contains larger particles in the form of relatively loose agglomerates, these agglomerates are reduced in size if their velocity of impact against the baffles is sufficiently high.

[0008] One disadvantage of the two sets of baffles described in GB 2191718 and PCT/EP93/00582 (WO-A-93/18811) is the high deposition of powder which can occur due to the baffles extending from the walls of the device at 90° to the direction of airflow. This may result in deposition of the larger agglomerates of powder occurring, which agglomerates could become loose in subsequent inhalations and result in variations in dosage.

[0009] It is an object of the invention to provide a device of the type just described which is simple for a user to operate and which is not unduly complex in its assembly. It is a further object to provide a device which may be filled with powder agglomerates but will deliver powder in a form suitable for administration by inhalation.

[0010] According to the invention there is provided a powder inhalation device comprising a housing containing a medicament, a conduit with an outlet extending into the housing through which a user can inhale to create an airflow through the conduit, a dosing unit for delivering a dose of the compound to the conduit and baffles arranged within the said conduit to aid disintegration of powder agglomerates entrained in said airflow, characterised in that the baffles comprise a plurality of staggered plates extending into the conduit from opposite sides of the conduit at an angle of less than 90° to the sides of the conduit and are inclined towards the outlet to create a plurality of constrictions within the conduit and a plurality of changes in the direction of the said airflow through the conduit.

[0011] By use of this arrangement it is possible to provide baffles which are simple to manufacture and provide low deposition of powder, and yet which give good results in breaking agglomerates down into discrete constituent particles to create a powder of respirable size.

[0012] Preferably the device contains at least 2 plates and more preferably 4 plates.

[0013] Preferably the said plates are inclined at an angle less than 70° to the longitudinal axis of the conduit in the direction of airflow and more preferably the said plates are inclined at an angle in the range of 15° to 50°.

[0014] Suitably the penultimate baffle is shaped so that at some point along the plate it divides into at least 2 faces, the first face of which continues to extend into the conduit and a second face of which extends towards the outlet substantially parallel to the longitudinal axis of the conduit. This enables the airflow to exit parallel to the said axis delivering the powder directly to the user's respiratory tract and not into the cheek cavity of the user.

[0015] An embodiment of the invention is further described below with reference to the accompanying drawings in which:

Figure 1 is a perspective view of an assembled device in accordance with the invention;

Figure 2 is an exploded perspective view of the device of Figure 1 showing the main body components and primary pack;

Figure 3 is an exploded perspective view of the device showing each component in disassembled form;

Figure 4 is a plan view partly in section showing air flow through a preferred embodiment of the invention;

Figure 5 is a perspective view showing airflow through the device shown in Figure 4; and

Figure 6 is a cut away view showing the pocket closure pad held in the raised position.

[0016] Suitable powdered medicaments to be used with the invention are, for example, for the treatment of asthma, and include salbutamol, beclomethasone, salmeterol, fluticasone, formoterol, terbutaline, budesonide and flunisolide, and physiologically acceptable salts, solvates and esters or any combination thereof. Preferred medicaments are salbutamol, salbutamol sulphate, salmeterol, salmeterol xinafoate, fluticasone propionate, beclomethasone dipropionate or solvates thereof and terbutaline sulphate. Other suitable powdered medicaments include antiviral medicaments, for example zanamivir (4-guanidino-Neu-5-Ac-2-en). It will be appreciated by those skilled in the art that the powder medicament, may, if desired, be a combination of two or more active ingredients. A dose may be constituted from the contents of one or more cavities and the size of each cavity will depend on the dose to be delivered. It is to be understood that the medicament powder may consist purely of one or more active ingredients, or there may additionally be a carrier, for example lactose powder.

[0017] For inhalation therapy it is essential that the largest possible quantity of primary particles inhaled is in the respirable range, that is smaller than 5 microns. In order to aid break-up of any powder agglomerates entrained in the air flow a series of baffles 9 are located in the mouthpiece section 8. As will be explained later, the position of the baffles are important. The baffles can be formed in a single moulding with the body, so affording consistent, controlled and repeatable tolerance. It will be understood that the number and exact dimensions of baffles present will depend on the powder being used and the strength of the forces holding the agglomerates together. For example, it has been found that four baffles achieved the required break up of powder agglomerates of zanamivir. It would be entirely straight forward for a skilled person to experiment with the baffle dimensions to obtain desired flow resistance for a particular powder.

[0018] Figures 4 and 5 show a preferred arrangement of baffles 9 comprising of a plurality of staggered flat plates which extend into the conduit at angles of 30° to the longitudinal axis of the conduit from opposite sides of the housing. Most of the baffles extend beyond the longitudinal axis of the conduit with the final baffle 25 in the direction of airflow stopping short of the axis. The penultimate baffle 26 in the direction of the airflow has an extended flat face 27 running parallel to the longitudinal axis of the conduit and extending towards the outlet. This enables the airflow to exit parallel to the said axis delivering the powder directly to the user's respiratory tract and not into the cheek cavity of the user.

[0019] As seen in Figure 5, baffles 9 are arranged to disrupt the smooth flow of air through the mouthpiece to create additional turbulence, cause the air flow to change direction several times to cause any agglomerates of powder to collide with the baffles, walls and other agglomerates, and constrict the air flow to increase the flow velocity. The air circulation produces eddy currents in the back waters of the baffles creating further collisions to aid in the break up of the powder agglomerates. This is shown. by the arrows representing air flow in Figure 5. All of these effects promote the disintegration of powder agglomerates entrained in the air flow to render the powder in a form suitable for inhalation therapy. The extended flat face 27 running parallel to the longitudinal axis of the conduit attached to the penultimate baffle in the direction of airflow enables the airflow to exit parallel to the said axis delivering the powder directly to the user's respiratory tract and not into the cheek cavity of the user.

[0020] It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto falling within the definitions of the claims.

Claims

1. A powder inhalation device comprising a housing containing a medicament, a conduit with an outlet extending into the housing through which a user can inhale to create an airflow through the conduit, a dosing unit for delivering a dose of the compound to the conduit and baffles arranged within the said conduit to aid disintegration of powder agglomerates entrained in said airflow, **characterised in that**, the baffles comprise a plurality of staggered plates extending into the conduit from opposite sides of the conduit at an angle of less than 90° to the sides of the conduit and are inclined towards the outlet to create a plurality of constrictions within the conduit and a plurality of changes in the direction of the said airflow through the conduit.

2. A device as claimed in claim 1, comprising at least 2 plates.

3. A device as claimed in claim 2, comprising 4 plates.

4. A device as claimed in any one of claims 1 to 3 wherein the said plates are inclined at an angle less than 70° to the longitudinal axis of the conduit in the direction of airflow.

5. A device as claimed in claim 4, wherein the said plates are inclined at an angle in the range of 15°

to 50°.

6. A device as claimed in claim 5 wherein the said plates are inclined at an angle of 30°.

7. A device as claimed in any one of claims 1 to 6, wherein the penultimate baffle is shaped so that at some point along the plate it divides into at least 2 faces, the first face of which continues to extend into the conduit and a second face of which extends towards the outlet substantially parallel to the longitudinal axis of the conduit.

8. A device as claimed in any preceding claim, wherein the medicament is zanamivir.

Patentansprüche

1. Puderinhalationsvorrichtung, umfassend ein Gehäuse, das ein Medikament enthält, eine Zuführung mit einem Auslass, die sich in das Gehäuse erstreckt, durch die ein Benutzer inhalieren kann, so dass eine Luftströmung durch die Zuführung erzeugt wird, eine Dosiereinheit zum Abgeben einer Dosis der Verbindung an die Zuführung und Prallflächen, die innerhalb der Zuführung angeordnet sind, um die Disintegration von Puderagglomeraten zu unterstützen, die in der Luftströmung eingeschlossen sind, **dadurch gekennzeichnet, dass** die Prallflächen eine Vielzahl von versetzten Prallflächen umfassen, die sich in die Zuführung von gegenüberliegenden Seiten der Zuführung unter einem Winkel von weniger als 90° zu den Seiten der Zuführung erstrecken und in Richtung auf den Auslass geneigt sind, so dass sie eine Vielzahl von Hindernissen in der Zuführung und eine Vielzahl von Richtungsänderungen der Luftströmung durch die Zuführung bilden.

2. Vorrichtung nach Anspruch 1, umfassend mindestens zwei Prallflächen.

3. Vorrichtung nach Anspruch 2, umfassend vier Prallflächen.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, wobei die Prallflächen unter einem Winkel von weniger als 70° zur Längsachse der Zuführung in der Richtung der Luftströmung geneigt sind.

5. Vorrichtung nach Anspruch 4, wobei die Prallflächen unter einem Winkel im Bereich von 15° bis 50° geneigt sind.

6. Vorrichtung nach Anspruch 5, wobei die Prallflächen unter einem Winkel von 30° geneigt sind.

7. Vorrichtung nach einem der Ansprüche 1 bis 6, wobei die vorletzte Prallfläche so gestaltet ist, dass an einem Punkt entlang der Prallfläche sie sich in mindestens zwei Flächen teilt, wobei die erste Fläche sich weiter in die Zuführung erstreckt und eine zweite Fläche sich in Richtung auf den Auslass im wesentlichen parallel zur Längsachse der Zuführung erstreckt.

8. Vorrichtung nach einem der vorstehenden Ansprüche, wobei das Medikament Zanamivir ist.

Revendications

1. Dispositif d'inhalation de poudre comprenant un boîtier contenant un médicament, un conduit doté d'un orifice de sortie s'étendant dans le boîtier, à travers lequel un utilisateur peut inhaler pour créer un écoulement d'air à travers le conduit, une unité de dosage pour délivrer une dose du composé vers le conduit, et des déflecteurs disposés à l'intérieur dudit conduit pour aider à la désintégration des agglomérats de poudre entraînés dans ledit écoulement d'air, **caractérisé en ce que** les déflecteurs comprennent une pluralité de plaques disposées en zigzag s'étendant à l'intérieur du conduit depuis les côtés opposés du conduit à un angle inférieur à 90° par rapport aux côtés du conduit et qui sont inclinées vers l'orifice de sortie pour créer une pluralité d'étranglements à l'intérieur du conduit et une pluralité de changements de direction dudit écoulement d'air à travers le conduit.

2. Dispositif selon la revendication 1, comprenant au moins deux plaques.

3. Dispositif selon la revendication 2, comprenant quatre plaques.

4. Dispositif selon l'une quelconque des revendications 1 à 3, dans lequel lesdites plaques sont inclinées à un angle inférieur à 70° par rapport à l'axe longitudinal du conduit dans la direction de l'écoulement d'air.

5. Dispositif selon la revendication 4, dans lequel lesdites plaques sont inclinées à un angle se trouvant dans la plage de 15° à 50°.

6. Dispositif selon la revendication 5, dans lequel lesdites plaques sont inclinées à un angle de 30°.

7. Dispositif selon l'une quelconque des revendications 1 à 6, dans lequel l'avant-dernier déflecteur est formé de sorte qu'à un certain point le long de la plaque, il se divise en au moins 2 faces, la première face continuant de s'étendre dans le conduit,

et une deuxième face s'étendant vers l'orifice de sortie substantiellement parallèlement à l'axe longitudinal du conduit.

8. Dispositif selon l'une quelconque des revendications précédentes, dans lequel le médicament est le zanamivir.

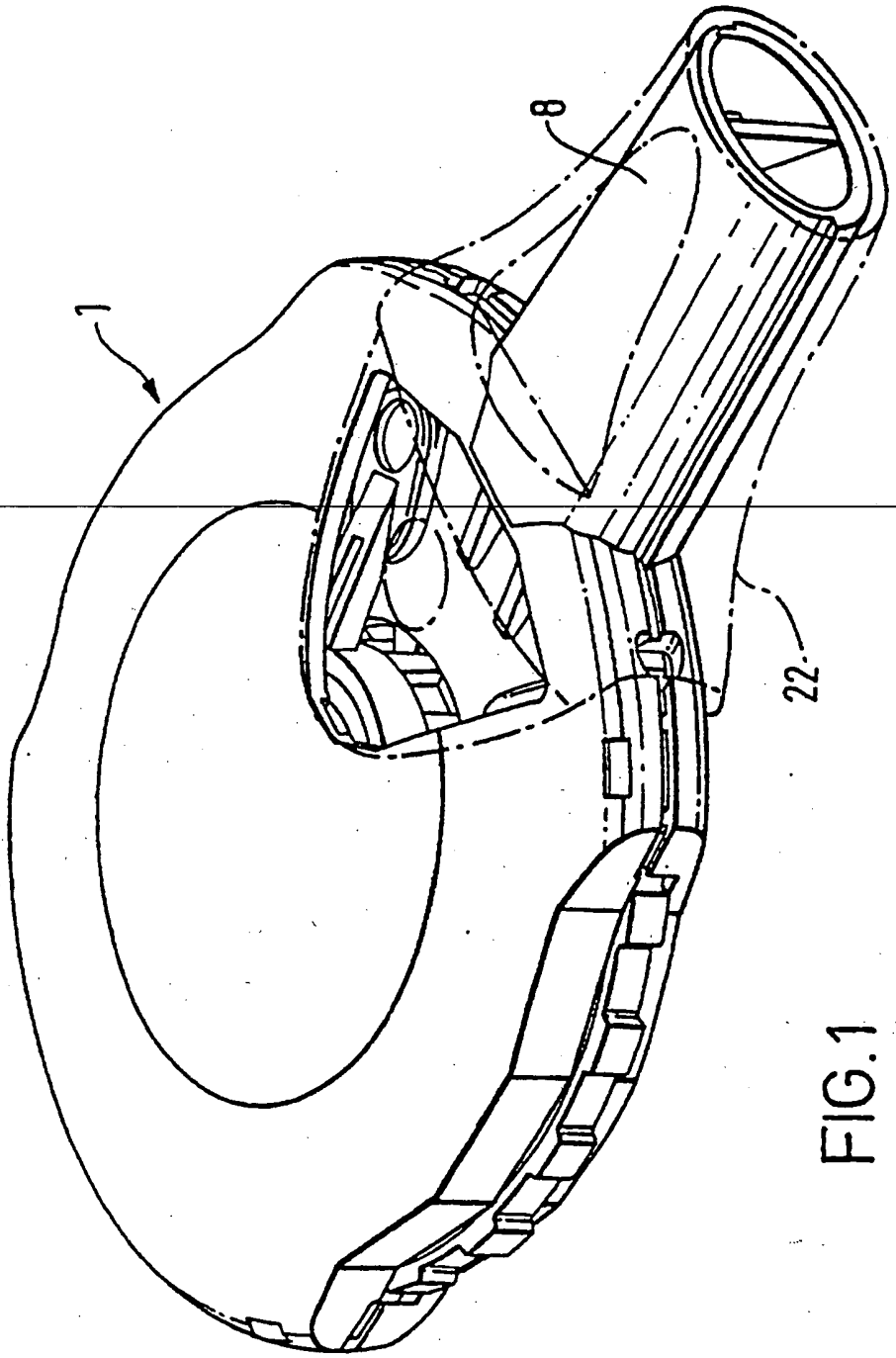


FIG.1

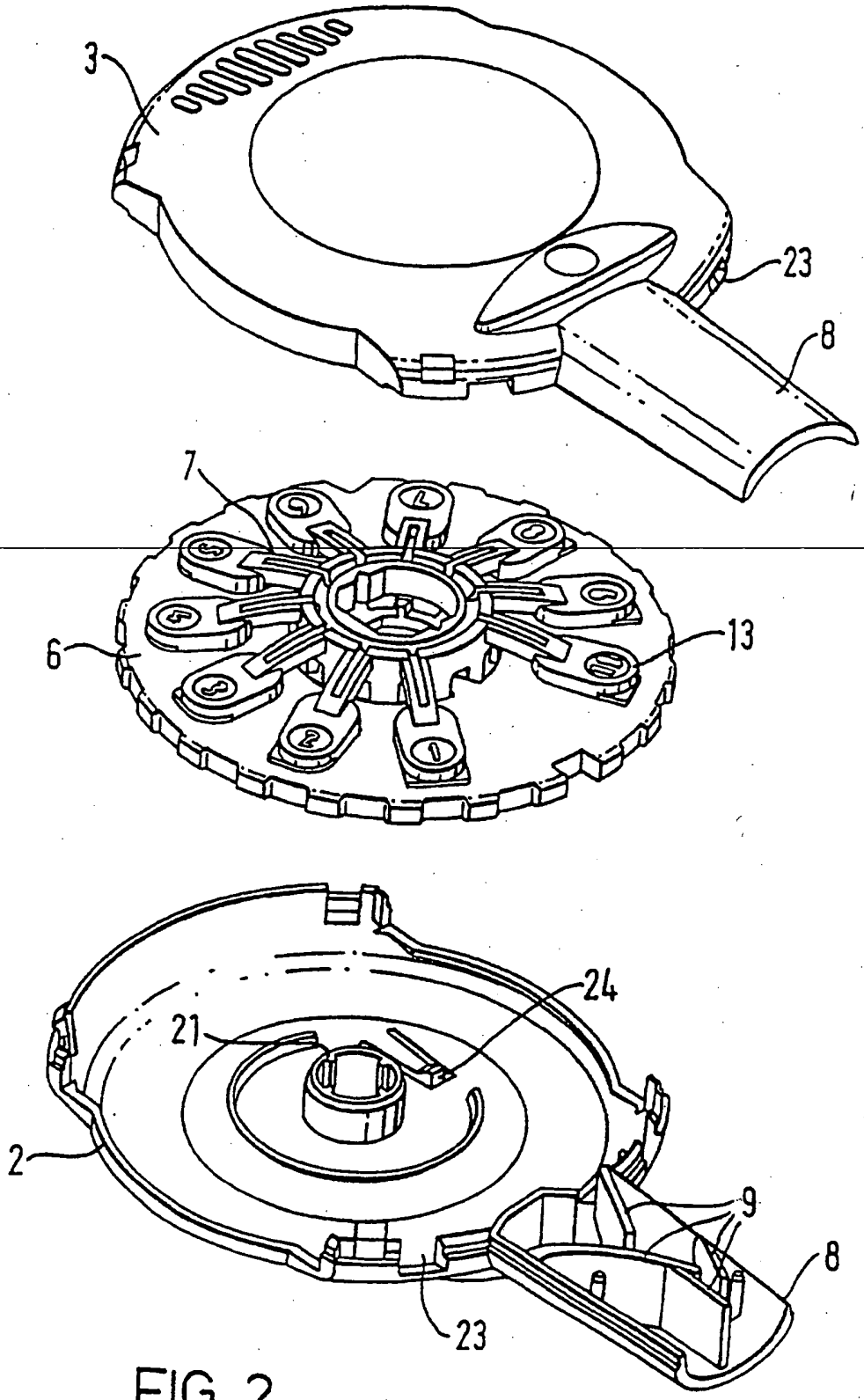
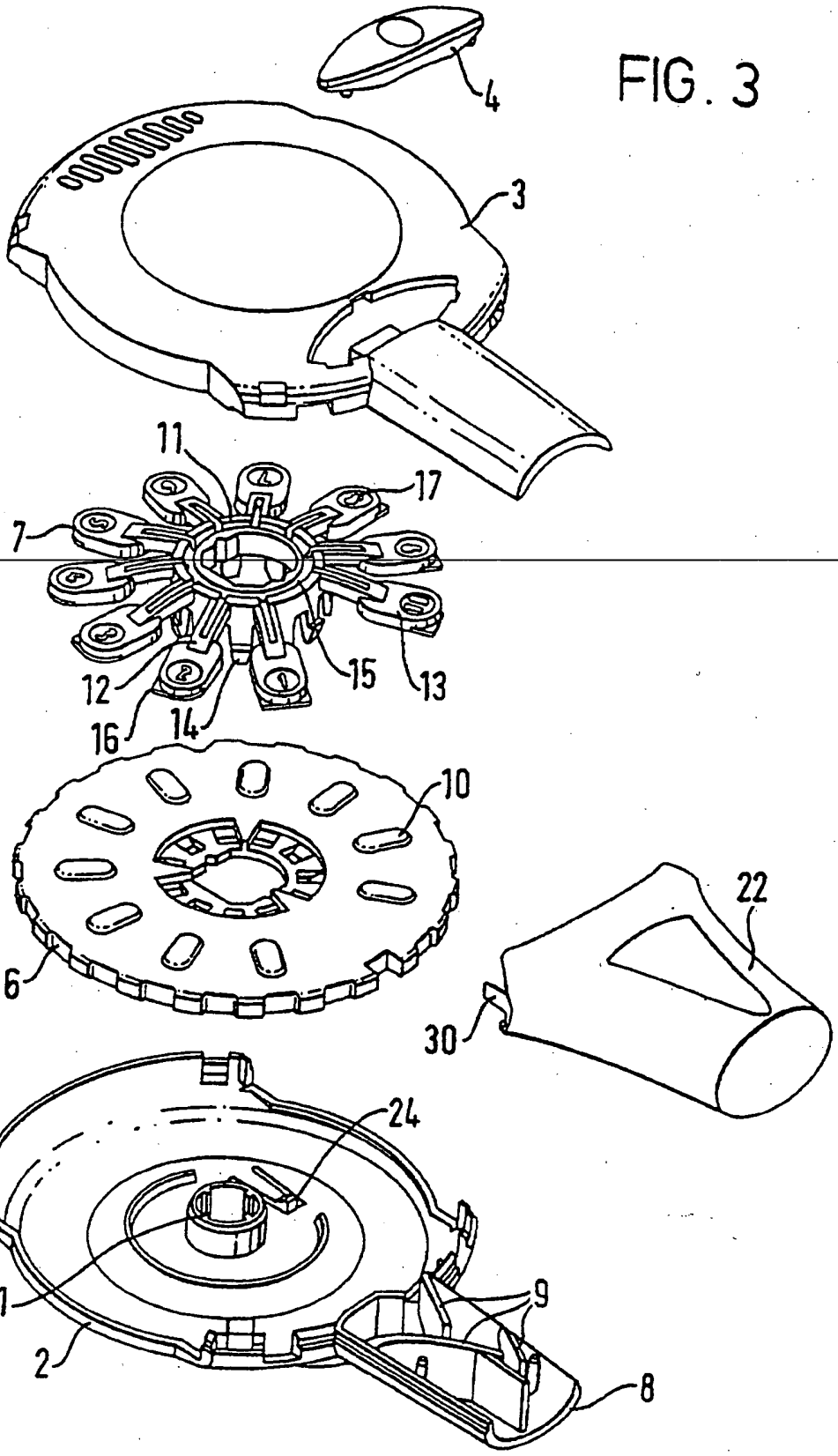


FIG. 2

FIG. 3



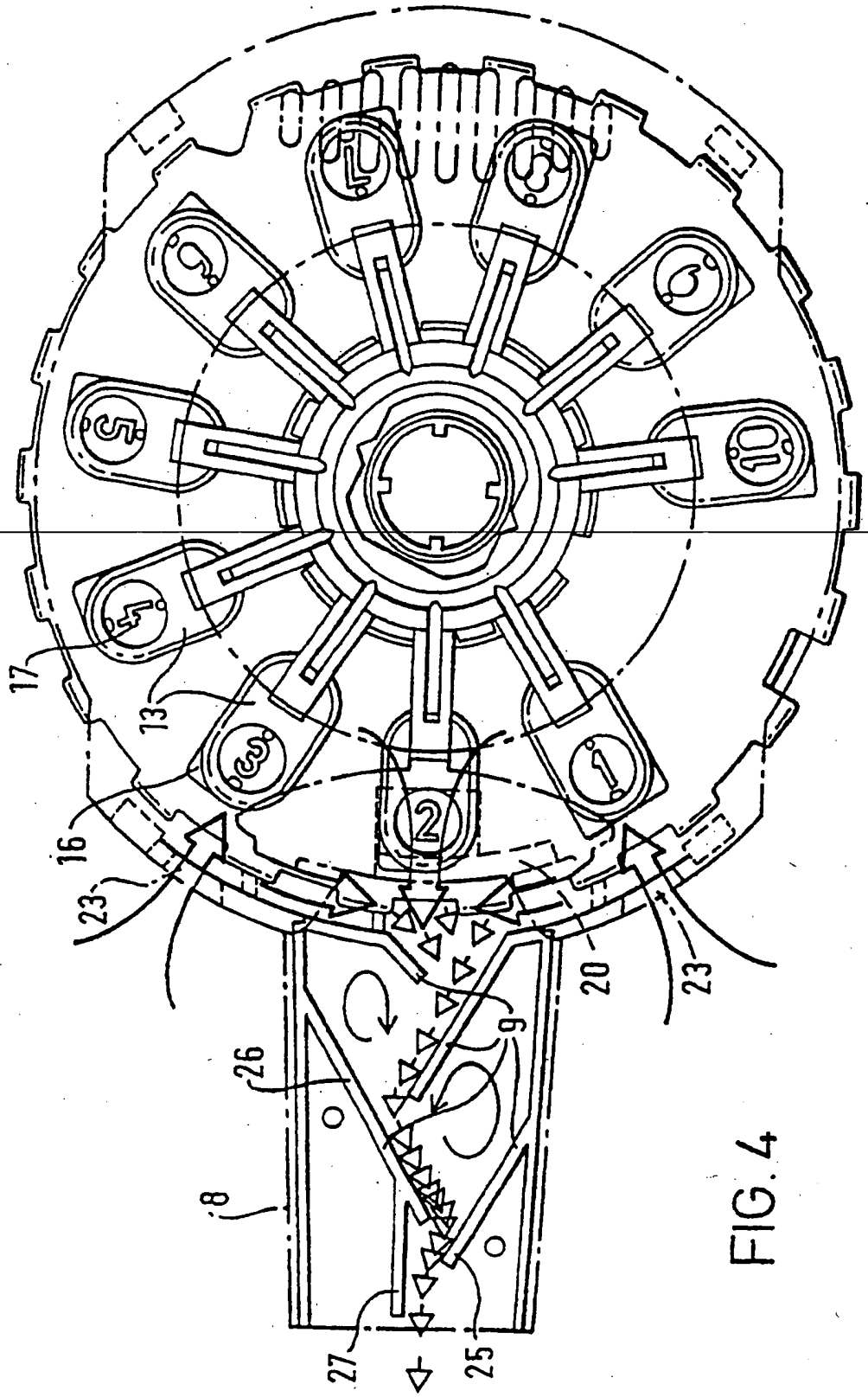


FIG. 4

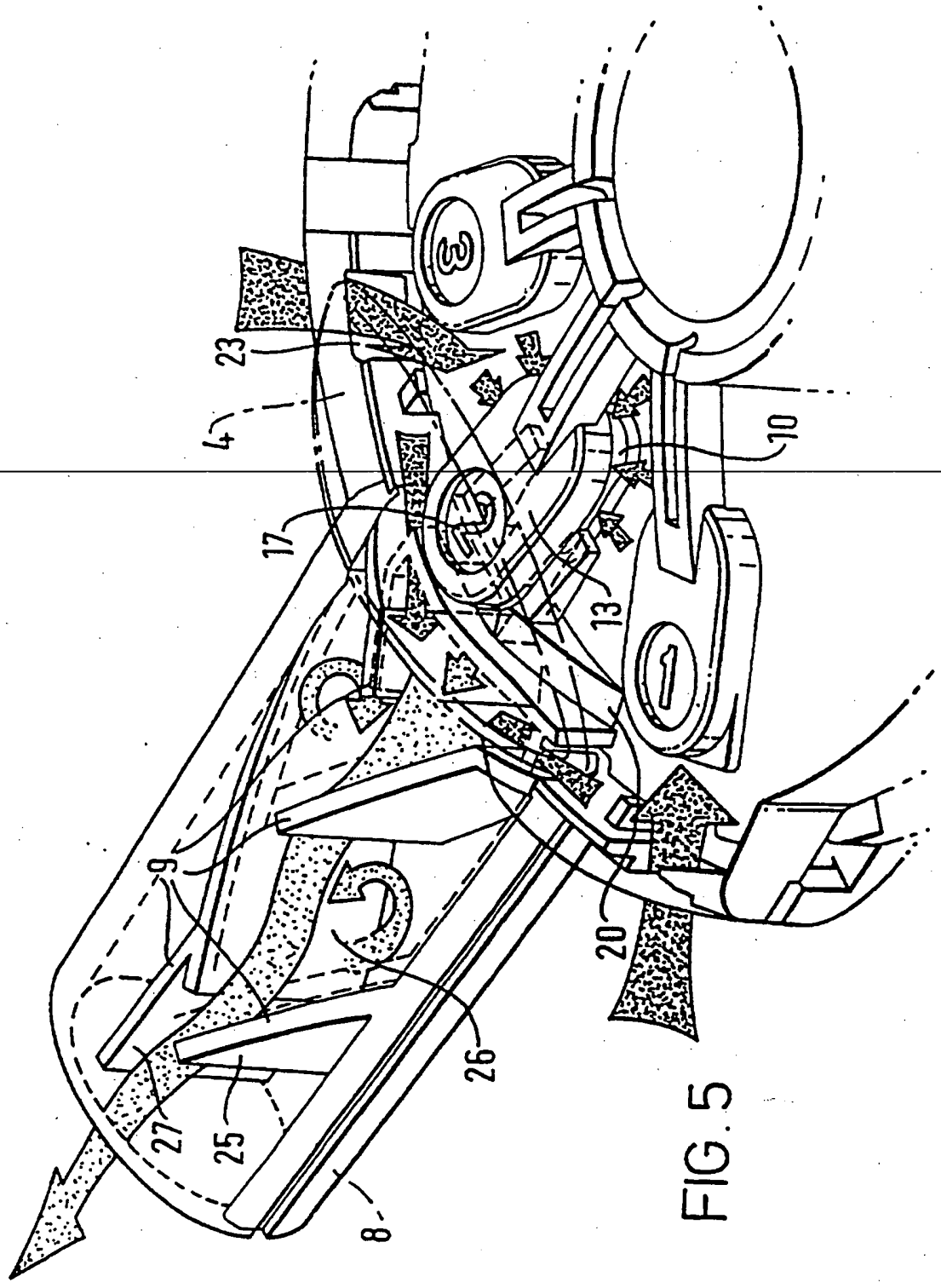


FIG. 5

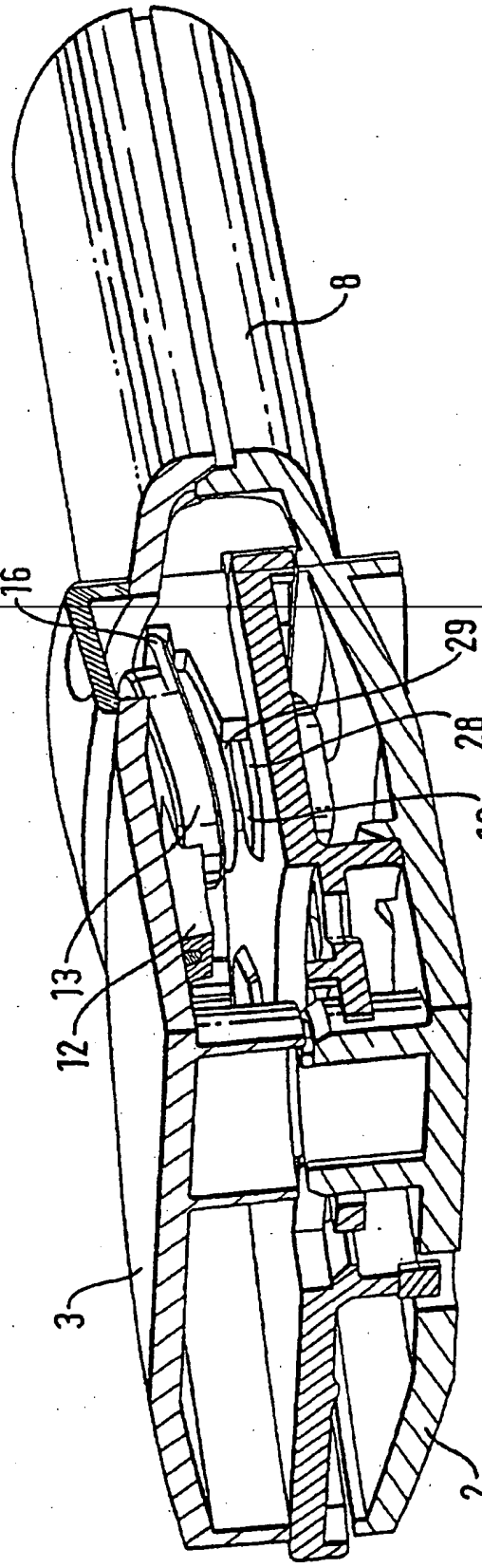


FIG. 6